

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|               |   |                   |                       |
|---------------|---|-------------------|-----------------------|
| Applicant:    | Denise L. Faustman  | Confirmation No.: | 3056                  |
| Serial No.:   | 10/698,734  | Art Unit:         | 1644                  |
| Filed:        | October 31, 2003  | Examiner:         | Michail A. Belyavskyi |
| Customer No.: | 21559   |                   |                       |
| Title:        | METHODS OF ORGAN REGENERATION USING HOX11-EXPRESSING<br>PLURIPOTENT CELLS |                   |                       |

APPLICATION FOR PATENT TERM ADJUSTMENT  
UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) set forth in the Issue Notification mailed in connection with the above-captioned patent application on August 12, 2009, and as set forth on the cover of U.S. Patent No. 7,582,313 B2 ("the '313 patent"), issued September 1, 2009, Applicant hereby requests reconsideration of the patent term adjustment. Applicant submits that the current patent term adjustment should be 725 days, not 199 days as shown in the Patent Term Adjustment History on the PAIR system (Exhibit A).

Background Law and Rules

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1). Applicant refers to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

\* \* \*

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). Applicant refers to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states (emphasis added):

**To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.**

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35 U.S.C.

§ 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), **the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154 (b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).**

Explanation of 37 C.F.R. § 1.703(f) and of the United States Patent and Trademark Office

Interpretation of 35 U.S.C. § 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004). The

Office’s interpretation was recently rejected by the U.S. District Court for the District of

Columbia, which stated (emphasis added):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” **The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.** Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

**The problem with the PTO’s construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.**

*Wyeth v. Dudas*, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063, at \*3 (D.D.C. Sept. 30, 2008).

Accordingly, Applicant submits that, where A delay occurs on different calendar days before the B delay, the periods of A delay and B delay are not to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

#### The '313 Patent

Two periods of A delay are shown in Exhibit A: The delay of 434 days associated with the mailing of the Restriction Requirement dated March 10, 2006, and the delay of 7 days associated with the mailing of the final Office Action dated January 24, 2008. Thus, according to Exhibit A, the total A delay is 441 days. Applicant believes the total A delay should only be 434 days; it is not clear to Applicant how the additional 7 days of delay were calculated by the Office.

Under 37 C.F.R. §§ 1.702(b) and 1.703(b), the time interval between the date that is three years from the actual filing date of the application and the filing of a Request for Continued Examination counts as B delay. As shown in Exhibit A, the Office's calculation of B delay is 636 days. Applicant does not dispute the Office's calculation.

As is discussed above, when the periods of A delay and B delay do not overlap, Applicant is entitled to both periods of delay. Here, the period of A delay – December 31, 2004 to March 10, 2006 – does not overlap with the period of B delay, which ran from October 31, 2006 to June 28, 2008. Accordingly, Applicant is entitled, under U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f), to the sum of the periods of A delay and B delay in the patent term adjustment calculation, for a total Office delay of  $434 + 636 = 1070$  days.

Turning to applicant delay, based on an analysis of 37 C.F.R. § 1.704, Applicant does not dispute the Office's calculation of 437 days.

Applicant concludes that the Office delay associated with the '313 patent is  $434 + 636 = 1070$  days, while the applicant delay is  $62 + 16 + 29 + 97 + 43 + 95 + 3 + 57 + 35 = 437$  days. Thus, the '313 patent is entitled to a total of  $1070 - 437 = 633$  days of patent **term** adjustment under 37 C.F.R. § 1.703, and such correction is hereby respectfully requested.

The present patent is not **subject to a Terminal Disclaimer**.

### CONCLUSION

For the above reasons, Applicant submits that the current patent **term** adjustment should be 633 days and requests reconsideration of the patent **term** adjustment.

Please charge Deposit Account No. 03-2095 in the amount of \$200.00 for the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Date: 28 October 2009

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10/698,734

**METHODS OF ORGAN REGENERATION USING HOX11-EXPRESSING PLURIPOTENT CELLS**

10-28-

2009::12:22:59

**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/698,734

|                              |            |                                      |     |
|------------------------------|------------|--------------------------------------|-----|
| Filing or 371(c) Date:       | 10-31-2003 | USPTO Delay (PTO) Delay (days):      | 636 |
| Issue Date of Patent:        | 09-01-2009 | Three Years:                         | -   |
| Pre-Issue Petitions (days):  | +0         | Applicant Delay (APPL) Delay (days): | 437 |
| Post-Issue Petitions (days): | +0         | Total PTA (days):                    | 199 |
| USPTO Adjustment(days):      | +0         | Explanation Of Calculations          |     |

**Patent Term Adjustment History**

| Date       | Contents Description                                       | PTO(Days) | APPL(Days) |
|------------|--|-----------|------------|
| 08-12-2009 | PTA 36 Months  | 195       |            |
| 09-01-2009 | Patent Issue Date Used in PTA Calculation                  |           |            |
| 07-30-2009 | Dispatch to FDC  | ↑         |            |
| 07-29-2009 | Workflow - Drawings Finished                               |           | 35         |
| 07-06-2009 | Email Notification   |           | ↑          |
| 07-01-2009 | TC Return to Pubs  |           | ↑          |
| 07-06-2009 | Mail Miscellaneous Communication to Applicant              |           | ↑          |
| 07-01-2009 | Miscellaneous Communication to Applicant - No Action Count |           |            |
| 05-18-2009 | Dispatch to FDC  |           |            |
| 05-12-2009 | Application Is Considered Ready for Issue                  |           |            |
| 05-11-2009 | Workflow - Drawings Finished                               |           | 57         |
| 05-11-2009 | Issue Fee Payment Verified                                 |           |            |
| 05-11-2009 | Issue Fee Payment Received                                 |           |            |
| 04-13-2009 | TC Return to Pubs  |           |            |
| 04-14-2009 | Email Notification   |           |            |
| 04-13-2009 | Mail Miscellaneous Communication to Applicant              |           |            |
| 04-09-2009 | Miscellaneous Communication to Applicant - No Action Count |           |            |
| 03-02-2009 | Sequence Forwarded to Pubs on Tape                         |           |            |
| 02-12-2009 | Mail Notice of Allowance                                   |           |            |
| 02-09-2009 | Document Verification                                      |           |            |
| 02-09-2009 | Notice of Allowance Data Verification Completed            |           |            |
| 02-09-2009 | Case Docketed to Examiner in GAU                           |           |            |
| 12-29-2008 | Information Disclosure Statement considered                |           |            |
| 01-26-2009 | Paralegal TD Accepted                                      |           |            |
| 12-29-2008 | Reference capture on IDS                                   |           |            |
| 12-29-2008 | Information Disclosure Statement (IDS) Filed               |           |            |
| 12-29-2008 | Terminal Disclaimer Filed                                  |           |            |
| 01-23-2009 | Date Forwarded to Examiner                                 |           |            |
| 12-29-2008 | Response after Non-Final Action                            |           | 3          |
| 12-29-2008 | Information Disclosure Statement (IDS) Filed               |           | ↑          |

|            |   |    |   |
|------------|---|----|---|
| 09-26-2008 | Electronic Review                                       |    | ⬆ |
| 09-26-2008 | Email Notification                                      |    | ⬆ |
| 09-26-2008 | Mail Non-Final Rejection                                |    | ⬆ |
| 09-24-2008 | Non-Final Rejection                                     |    |   |
| 08-20-2008 | Reference capture on IDS                                |    |   |
| 08-20-2008 | Information Disclosure Statement (IDS) Filed            |    |   |
| 08-20-2008 | Information Disclosure Statement considered             |    |   |
| 08-20-2008 | Information Disclosure Statement (IDS) Filed            |    |   |
| 08-08-2008 | Date Forwarded to Examiner                              |    |   |
| 08-08-2008 | Date Forwarded to Examiner                              |    |   |
| 07-28-2008 | Request for Continued Examination (RCE)                 | 95 |   |
| 08-08-2008 | DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA) |    | ⬆ |
| 07-28-2008 | Request for Extension of Time - Granted                 |    | ⬆ |
| 07-28-2008 | Workflow - Request for RCE - Begin                      |    | ⬆ |
| 01-25-2008 | Electronic Review                                       |    | ⬆ |
| 01-24-2008 | Email Notification                                      |    | ⬆ |
| 01-24-2008 | Mail Final Rejection (PTOL - 326)                       | 7  |   |
| 01-18-2008 | Final Rejection   |    | ⬆ |
| 09-17-2007 | Information Disclosure Statement considered             |    | ⬆ |
| 07-05-2007 | Information Disclosure Statement considered             |    | ⬆ |
| 11-27-2007 | Date Forwarded to Examiner                              |    | ⬆ |
| 10-30-2007 | Supplemental Response                                   | 43 |   |
| 09-17-2007 | Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received   |    | ⬆ |
| 09-25-2007 | Date Forwarded to Examiner                              |    | ⬆ |
| 09-17-2007 | Response after Non-Final Action                         | 97 |   |
| 09-17-2007 | Request for Extension of Time - Granted                 |    | ⬆ |
| 09-17-2007 | Information Disclosure Statement (IDS) Filed            |    | ⬆ |
| 09-17-2007 | Information Disclosure Statement (IDS) Filed            |    | ⬆ |
| 07-05-2007 | Reference capture on IDS                                |    | ⬆ |
| 07-05-2007 | Electronic Information Disclosure Statement             |    | ⬆ |
| 07-05-2007 | Information Disclosure Statement (IDS) Filed            |    | ⬆ |
| 03-12-2007 | Mail Non-Final Rejection                                |    | ⬆ |
| 03-02-2007 | Non-Final Rejection                                     |    |   |
| 08-25-2004 | Information Disclosure Statement considered             |    |   |
| 01-18-2007 | Date Forwarded to Examiner                              |    |   |
| 12-27-2006 | Response to Election / Restriction Filed                | 29 |   |
| 12-27-2006 | Request for Extension of Time - Granted                 |    | ⬆ |
| 08-28-2006 | Mail Restriction Requirement                            |    | ⬆ |
| 08-18-2006 | Requirement for Restriction / Election                  |    |   |
| 07-07-2006 | Date Forwarded to Examiner                              |    |   |
| 06-26-2006 | Response to Election / Restriction Filed                | 16 |   |

|            |  |     |    |
|------------|--|-----|----|
| 06-26-2006 | Request for Extension of Time - Granted  |     | ⬆  |
| 03-10-2006 | Mail Restriction Requirement   | 434 | ⬆  |
| 03-06-2006 | Requirement for Restriction / Election   |     | ⬆  |
| 10-18-2005 | IFW TSS Processing by Tech Center Complete   |     | ⬆  |
| 10-18-2005 | Case Docketed to Examiner in GAU   |     | ⬆  |
| 12-27-2004 | Preliminary Amendment  |     | ⬆  |
| 08-25-2004 | Information Disclosure Statement (IDS) Filed   |     | ⬆  |
| 08-25-2004 | Information Disclosure Statement (IDS) Filed   |     | ⬆  |
| 04-13-2005 | Application Dispatched from OIPE   |     | ⬆  |
| 04-13-2005 | Application Is Now Complete  |     | ⬆  |
| 03-21-2005 | Additional Application Filing Fees   |     | 62 |
| 03-21-2005 | CRF Disk Has Been Received by Preexam / Group / PCT  |     | ⬆  |
| 04-04-2005 | CRF Is Good Technically / Entered into Database  |     | ⬆  |
| 01-19-2005 | SEQUENCE ERRORS  |     | ⬆  |
| 12-22-2004 | CRF Disk Has Been Received by Preexam / Group / PCT  |     | ⬆  |
| 12-22-2004 | Additional Application Filing Fees   |     | ⬆  |
| 12-22-2004 | A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in |     | ⬆  |
| 12-22-2004 | A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic |     | ⬆  |
| 01-06-2005 | CRF Is Flawed Technically / Not Entered into Database  |     | ⬆  |
| 10-18-2004 | Notice Mailed--Application Incomplete--Filing Date Assigned  |     | ⬆  |
| 01-22-2004 | Cleared by OIPE CSR  |     |    |
| 12-21-2003 | IFW Scan & PACR Auto Security Review   |     |    |
| 10-31-2003 | Initial Exam Team nn   |     |    |

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